**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-998/S-059

Merck and Company, Inc.
Attention: Michael C. Elia, Ph.D.
Director, Regulatory Affairs
P. O. Box 4
Sumneytown Pike, BLA-20
West Point, PA 19486

Dear Dr. Elia:

Please refer to your supplemental new drug application dated January 14, 2000, received January 14, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Vasotec (enalapril maleate) 2.5, 5, 10, and 20 mg Tablets.

We acknowledge receipt of your submission dated December 21, 2000 that constitutes a complete response to our August 28, 2000 approvable letter.

This supplemental new drug application provides for final printed labeling revised to include information on pediatric use. In addition, minor editorial changes have been made under **CLINICAL PHARMACOLOGY**/*Pediatric Patients*, **DOSAGE AND ADMINISTRATION**/Pediatric Hypertensive Patients/*Preparation of Suspension (for 200 mL of a 10 mg/mL suspension)*, and throughout the **HOW SUPPLIED** section**.**

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert included in your December 21, 2000 submission). Accordingly, the supplemental application is approved effective on the date of this letter.

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact:

Sandra L. Birdsong
Regulatory Health Project Manager
(301) 594-5334

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Rockville MD 20857

Sincerely,

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research